



CONNOLLY BOVE LODGE & HUTZ LLP

ATTORNEYS AT LAW

The Nemours Building
1007 North Orange Street
P.O. Box 2207
Wilmington DE 19899
TEL (302) 658 9141
FAX (302) 658 5614

1990 M Street, NW, Suite 800
Washington DC 20036
TEL (202) 331 7111
FAX (202) 293 6229

WEB www.cbhlh.com

Francis DiGiovanni
Partner

TEL (302) 888-6316
FAX (302) 658-5614
EMAIL fdigiovanni@cbhlh.com
REPLY TO Wilmington Office

June 28, 2005

Date of Redacted Version: [July 6, 2005]

VIA HAND DELIVERY

The Honorable Kent A. Jordan
U.S. District Court for the District of Delaware
844 North King Street
Wilmington, Delaware 19801

**[REDACTED VERSION
DOCKET ITEM 53]**

Re: *Glaxo Group Limited v. Teva Pharmaceuticals USA, Inc. et al.*,
Civil Action No. 04-171-KAJ

Dear Judge Jordan:

This letter raises discovery issues that were first brought to the Court's attention on February 25 and March 31, 2005. Plaintiff patentee, Glaxo Group Limited ("Glaxo"), is faced with a refusal by defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") to: (i) admit, without qualification, that its accused product meets all of the claim limitations in Glaxo's U.S. Patent No. 5,068,249 (the "'249 patent," attached as Exh. 1) except for the disputed "ethanol" limitation in claims 1, 2, 3 and 11; and (ii) produce essential discovery that is highly relevant to the issues in this case. Teva's refusal to abide in good faith by the Court's instruction during the February 25, 2005 teleconference (*see* Exh. 2, Tr. pg. 20 lines 9-24) to provide a written confirmation narrowing the issues for trial is significantly impacting Glaxo's ability to develop its patent infringement case within the timeframe set forth in the Court's Scheduling Order. Glaxo's attempts, since September 2004, to obtain basic and fundamentally relevant discovery on the remaining issues also have been frustrated at every turn by Teva's lack of cooperation.

1. Defendant's Refusal to Admit the Non-Ethanol Claim Limitations in the '249 Patent

The '249 patent is directed to the use of a stabilizing effective amount of ethanol to stabilize ranitidine, or its physiologically acceptable salts, in an oral aqueous formulation. Glaxo respectfully refers the Court to the second paragraph of Glaxo's February 22 letter to the Court for a more complete explanation of the patented technology.

During the parties February 25 teleconference with Your Honor, Teva's counsel committed to confirm in writing, by supplementing Teva's response to Glaxo's Interrogatory No. 6, Teva's admission that its accused product meets all of the '249 patent claim limitations with the exception of the equivalence of [REDACTED] to the claimed "ethanol" limitation. Teva's agreement was in exchange for Glaxo's agreement to limit infringement discovery to the so-called "ethanol" claim

The Honorable Kent A. Jordan
 June 28, 2005
 Page 2

limitation. As the Court noted: "So the only thing in issue, you're [Teva] going on the record right now to say the only thing that you are saying is different about the formation of your client's product is this one distinction that the plaintiff has drawn between the substitution of ethanol for the [REDACTED] [REDACTED] is that right?" To which Mr. Schuman responded "Yes, Your Honor." Transcript at page 20. Defendant's Amended Responses to Glaxo's Interrogatory Nos. 6 and 7, however, are hedged and couched in a manner that, in Glaxo's view, is unsatisfactory. (Teva Responses attached as Exh. 3). Teva's answers are not what the Court ordered or what Glaxo contemplated based on Teva's above-quoted exchange with the Court.

Glaxo then prepared and served Requests for Admission to narrow the issues for discovery and trial. Glaxo's requests were met with further hedging in the form of numerous objections and qualified admissions. (Teva's Responses attached as Exh. 4). Teva apparently takes the view that since the Court has not yet construed the language of the '249 patent claims, it cannot make unqualified admissions. Glaxo asks for an Order that Teva either admit, without qualification, Glaxo's Requests for Admission Nos. 1-3, 6, 11-21 and 24 (that its accused, generic ranitidine oral solution product meets all of the non-ethanol claim limitations) or produce immediately all discovery directed by Glaxo to all of the '249 claim limitations.

2. Teva's Refusal to Produce the Novopharm Formulation Documents

The issue we addressed previously, and revisit now, focuses on Teva's use of [REDACTED] as an equivalent for ethanol in its generic ranitidine oral solution formulation. Teva's subsidiary, Novopharm Limited ("Novopharm"), actually developed the formulation, but after nine months of repeated, specific requests for all of the relevant Novopharm formulation documents, including certain unproduced portions of Novopharm's ANDA for ranitidine oral solution, we have been given some, but not all, of the extent documents.

Teva identified in its Initial Disclosures served on August 12, 2004, and two recent depositions confirm, that highly relevant Novopharm documents exist regarding Novopharm's selection of [REDACTED] as the equivalent of choice used in the formulation of Teva's generic ranitidine oral solution. Glaxo seeks these documents because they are evidence of infringement and evidence of the validity and nonobviousness of the '249 patent. *Glaxo Wellcome, Inc. v. Pharmdyne Corp.*, 32 F. Supp. 2d 265, 284-87 (D. Md. 1998). The choices made in the formulation and development of the accused product and the alternative pathways tried and abandoned (*e.g.*, unsuccessful efforts to design around the patented invention) are key indicia of infringement and validity. *See id.* The formulation and development work can provide highly relevant evidence of infringement (*e.g.*, how and why [REDACTED] was used as a substitute for ethanol; what effect the amount of [REDACTED] has on stability; what alternatives were tried; what problems were encountered/overcome) and can be probative of secondary indicia of non-obviousness (*e.g.*, copying, long-felt need, lack of viable alternatives). *See id.*

Glaxo has identified the specific documents repeatedly, most recently in two letters dated June 6, 2005, following the depositions of a Teva witness and a Novopharm witness, and a letter dated June

The Honorable Kent A. Jordan
 June 28, 2005
 Page 3

20, 2005. (Letters attached as Exhs. 5, 6, and 7). Teva has not yet responded. Glaxo requests an Order that Teva produce immediately the documents requested in the letters attached, especially the following documents: testing and development reports, lab notebooks, experimental data and analyses for batches 3G-0431, 1853-005, 1853-015, 1853-017, 3213PD and 399-01 through 399-10 (formulations utilizing varying concentrations of [REDACTED]). In the alternative, Glaxo requests the Court consider an appropriate sanction (e.g., entry of a Judgment of patent infringement) under Fed. R. Civ. P. 37(b) and (c).

3. Request for Ruling on Non-Party Evidence

Glaxo has notified counsel for Teva that Glaxo intends to admit evidence from the Pharmadyne trial at the trial of this case, including the relevant deposition and trial testimony and exhibits of Pharmadyne formulators Drs. Anita K. Runyan, Prasad Gullapalli and Nitin Pathak. This evidence is highly relevant to the equivalence of [REDACTED] and ethanol and the secondary indicia of non-obviousness supporting the validity of the '249 patent. Teva also has made several broad document requests for the evidence from the trial of the *Pharmadyne* matter, and that evidence has been made available to counsel for Teva. It is Glaxo's position that these documents are admissible pursuant to Fed. R. Evid. 804(b)(1), and that the aforementioned personnel are unavailable as that term is defined by Fed. R. Evid. 804(a)(5). The litigations against Teva and Pharmadyne involve [REDACTED] and have defendants with the same interests and motivations. Please see *Hill v. Equitable Bank National Assoc.*, 115 F.R.D. 184, 185-86 (D. Del. 1987) ("The presence of another adversary with the same motive to cross-examine, coupled with a substantial identity of issues would permit this Court to admit the deposition from a different action to this action." citing *George Whitten, Jr., Inc. v. State University Const. Inc.*, 359 F. Supp. 1037, 1039 (D. Mass. 1973), *aff'd on other grounds*, 493 F.2d 177 (1st Cir. 1974)). Thus, further depositions of Anita Runyan, Prasad Gullapalli, and Nitin Pathak should not be required as a precondition to the admissibility of the Pharmadyne trial evidence at the trial of this case against Teva. Glaxo respectfully requests an Order confirming the admissibility of the Pharmadyne trial evidence without requiring further deposition testimony of the Pharmadyne witnesses.

Respectfully submitted,

/s/ Francis DiGiovanni

Francis DiGiovanni

cc: Clerk of the Court (by hand)
 Josy W. Ingersoll, Esq. (by hand)
 Mark D. Schuman, Esq. (via e-mail)
 Brian P. Murphy, Esq. (via e-mail)

Enclosures
 FD/dhd
 403659v1